6699. Safe-T-Sun lamp. (F.D.C. No. 44665. S. No. 3-379 R.)

QUANTITY: 13 individually ctnd. lamps at York, Pa.

SHIPPED: 4-16-60, from Adwolfe (Marion), Va., by American Atlas Corp.

LABEL IN PART: (Floor stand) "Health Tan Lamp, American Atlas Corp. * * * Adwolfe Road, Va."; (filter) "Safe-T-Sun Lamp Filter * * * Manufactured by American Atlas, Marion, Va."; (envelope) "Health Tan Sun Lamp Filter * * * Sun Tan and Never Burn American Atlas Corporation, Marion, Virginia."

ACCOMPANYING LABELING: Booklet entitled "Summer Sun Rays When and Where You Want Them"; instruction sheet reading in part: "Instructions for Unpacking, Assembling, and Operating the Safe-T-Sun Lamp"; and pamphlet reading in part "Health Tan Lamp."

RESULTS OF INVESTIGATION: One sunlamp was assembled and the other 12 were unassembled. The assembled article consisted of an ultraviolet lamp fitted with a polyester film filter and adjustable reflector. The unit was then fitted to a floor stand.

LIBELED: 6-14-60, M. Dist. Pa.

CHARGE: 502(a)—when shipped, the labeling accompanying the article contained false and misleading representations that the article was an adequate and effective treatment for producing vitamin D to build strong bones and teeth; that the article would provide a healthful suntan, promote health of children, and provide the sunshine vitamins; and that the filter used with the lamp would allow the passage to the body of 90 percent of the light rays above 3100 angstroms to provide artificial sunlight.

DISPOSITION: 7-15-60 and 10-3-60. Default—3 devices delivered to Food and Drug Administration and remainder destroyed.

DRUG ACTIONABLE BECAUSE OF FAILURE TO COMPLY WITH PACKAGING REQUIREMENTS OF AN OFFICIAL COMPENDIUM

6700. Procaine penicillin G. (F.D.C. No. 45871. S. No. 73-767 R.)

QUANTITY: 12 boxes of 8 ctns. of 100 vials each, at Los Angeles, Calif.

SHIPPED: 4-26-61, from Philadelphia, Pa., by Philadelphia Laboratories, Inc.

LABEL IN PART: (Vial) "10 cc. Multiple Dose Vial * * * 3,000,000 Units Procaine Penicillin G Crystalline U.S.P. * * * Phila. Laboratories, Inc., Phila. 23, Pa."

LIBELED: 7-14-61, S. Dist. Calif.

CHARGE: 502(g)—when shipped, the article purported to be *procaine penicillin G*, a drug, the name of which is recognized in the United States Pharmacopeia, an official compendium, and the article was not labeled as prescribed therein, since such compendium provides that *procaine penicillin G* conform to the regulations of the Federal Food and Drug Administration concerning certification of antibiotic drugs, whereas, the label of the article failed to bear lot numbers and expiration dates as required by regulations of the Federal Food and Drug Administration concerning certification of antibiotic drugs.

DISPOSITION: 8-23-61. Default—destruction.

U.S. Department of Health, Education, and Welfare

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

6701–6740

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by United States attorneys, acting upon reports submitted by the Department of Health, Education, and Welfare. They involve drugs and devices which were adulterated or misbranded within the meaning of the Act when introduced into and while in interstate commerce or while held for sale after shipment in interstate commerce. These cases involve (1) seizure proceedings in which decrees of condemnation were entered after default or consent; and (2) an injunction proceeding terminated upon the entry of a temporary injunction by consent. The seizure proceedings are civil actions taken against the *goods* alleged to be in violation, and the injunction proceeding was against the *firm* and *individual* charged to be responsible for violations.

Published by direction of the Secretary of Health, Education, and Welfare.

GEO. P. LARRICK, *Commissioner of Food and Drugs.*

WASHINGTON, D.C., *August 30, 1962.*

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*For an imitation, and sale under name of, another drug, see No. 6712; failure to bear a label containing the name and place of business of the manufacturer, packer, or distributor, Nos. 6707, 6722.

SECTIONS OF FEDERAL FOOD, DRUG, AND COSMETIC ACT INVOLVED IN VIOLATIONS REPORTED IN D.D.N.J. NOS. 6701–6740

Adulteration, Section 501(b), the article purported to be and was represented as a drug, the name of which is recognized in an official compendium (United States Pharmacopeia), and its quality fell below the standard set forth in such compendium; Section 501(c), the article was not subject to the provisions of Section 501(b), and its strength differed from, or its quality fell below, that which it purported or was represented to possess; and Section 501(d)(2), the article was a drug, and a substance had been substituted wholly or in part therefor.

Misbranding, Section 502(a), the labeling of the article was false and misleading; Section 502(b)(1), the article was in package form, and it failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor; Section 502(f), the labeling of the article failed to bear (1) adequate directions for use, and (2) adequate warnings against use in those pathological conditions, or by children, where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users; Section 502(i)(2), the article was an imitation of another drug; Section 502(i)(3), the article was offered for sale under the name of another drug; Section 502(j), the article was dangerous to health when used in the dosage, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof; Section 503(b)(4), the article was a drug subject to Section 503(b)(1), and its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

New-drug violation, Section 505(a), the article was a new drug within the meaning of Section 201(p), which was introduced into interstate commerce, and an application filed pursuant to Section 505(b) was not effective with respect to such drug.

DRUGS ACTIONABLE BECAUSE OF POTENTIAL DANGER WHEN USED ACCORDING TO DIRECTIONS

6701. Doxifer tablets and syrup. (F.D.C. No. 45806. S. Nos. 32–278/9 R.)

QUANTITY: 647 100-tablet btls. of *Doxifer Hematinico* and 215 8-oz. btls. of *Jarabe Doxifer-Hematinico*, at Santurce, P.R.

SHIPPED: 10–26–60 and 1–4–61, from Forest Hills, N.Y., by American Medicinal Corp.

LABEL IN PART: (Btl.) "Doxifer-Hematinico Formula – Cuatro Tabletas Contiene—Acido Folico 1.5 MG.—Dosis Sugerida: Adultos, 1 tableta cuatro veces al dia—American Medicinal Corporation, Forest Hills, New York – 49959" and (btl.) "Jarabe Doxifer-Hematinico De cuatro cucharaditas /20 cc./ Contiene – acido folico 1.5 mg.—Dosis sugerida: Adultos, 1 cucharadita cuatro veces al dia – American Medicinal Corporation Forest Hills, New York – 01049."

LIBELED: 5–18–61, Dist. P.R.

CHARGE: 502(j)—when shipped, the articles were dangerous to health when used in the dosage, or with the frequency or duration prescribed, recommended, or suggested in the labeling, since the articles under the directions for use, would supply 1.5 mg. of folic acid daily.

DISPOSITION: 8–8–61. Consent—destruction.